

**The Negotiated Rulemaking Committee on Special Payment Provisions
for Prosthetics and Certain Custom-Fabricated Orthotics Meeting**
October 29-31, 2002 - Meeting #2

Day 1 – October 29, 2002

The second Negotiated Rulemaking Committee on Special Payment Provisions for Prosthetics and Certain Custom-Fabricated Orthotics meeting convened on October 29, 2002, at the Pikesville Hilton in Pikesville, Maryland. The meeting was called to order at 9:00 a.m. by facilitators Lynn Sylvester and Ira Lobel, who immediately distributed a sign-in sheet for committee members' signature (Attachment 2-1). The committee was also asked to provide updated contact information on the facilitators' official member roster. The meeting began with committee members reviewing the meeting minutes from the first meeting. After noting minor editorial changes, the minutes were approved by consensus. The group was informed that the final version of the minutes from the first meeting would be posted to the Center for Medicare and Medicaid Services' (CMS) website at: <http://www.cms.hhs.gov/faca/prosthetic>.

Before reviewing the agenda for the meeting, the facilitators informed the group that hotel accommodations could not be secured for the December 2-3, 2002 meeting. As a result of the lack of hotel availability, the group will not meet in December.

Based on the recommendation from a committee member, the committee agreed to reserve 5 minutes at the conclusion of each day to hear public comments. Consensus having been met, this decision replaces the previous rule as stated in the committee's ground rules. An additional modification to the committee's ground rules was the inclusion of a signature from the representative of the American Academy of Physical Medicine and Rehabilitation (PM&R).

Committee member John Michael reported the findings from the sub-group that was asked to address the issue of disclosing committee members' inter-organizational affiliations, e.g., membership, offices held. The sub-group recommended that a spreadsheet be created to capture committee members' relationships with other organizations represented on the committee. The committee agreed by consensus that each primary and alternate member would disclose in writing any membership (or credential status) and/or leadership role(s) they hold or have previously held in organizations represented on the committee. John Michael agreed to finalize a spreadsheet based on committee recommendations for distribution to the committee before the meeting's end. In addition, as applicable, committee members agreed to provide their organizational web addresses as a vehicle to further disclose inter-relationships among its members. The following web address were provided:

Organization	Web Address
NAAOP	OandP.com/naaop
BOC	bocusa.org
AOPA	aopanet.org
AIE	amp-info.org
APTA	apta.org
NCOPE	ncope.org
NASL	nasl.org
ABC	ABCOP.org
Barr Foundation	oandp.com/barr
AOTA	aota.org
Hanger	hanger.com
AAOS	aaos.org
IAOP	iaop.org

After a short break the group reconvened to hear presentations from representatives of the American Board for Certification in Orthotics and Prosthetics (ABC), and the Board for Orthotist/Prosthetist Certification (BOC). William DeToro, ABC Representative, provided an overview of ABC including its history, mission, education milestones, accreditation standards, and credentialing programs (Attachment 2-5). After his presentation, Mr. DeToro responded to numerous questions from the committee, among which included:

Q: Does ABC accredit manufacturers?

A: No.

Q: Is there a maximum on the number of facilities a credentialed professional can supervise?

A: No, but he/she must be able to get to the facility within 60 minutes.

Q: How long is a practitioner credentialed for?

A: After 5 years the credentials have to be renewed by accumulating a specified number of CEUs. This demonstrates continued education.

Q: How many Orthotists and Prosthetists do you credential each year?

A: Approximately 240 practitioners are certified each year.

Q: Do all your credential programs require a minimum of college degree?

A: Registered technicians and assistants are not required to have a baccalaureate degree.

Q: Does your canons of ethics address problems that a practitioner might see in a facility in which he/she is working?

A: Yes

Q: What is the attrition rate of your practitioners?

A: Approximately 1% gets out of the field through attrition.

Q: Since 1948, how many certifications has ABC revoked?

A: Twelve have been revoked. (Information provided on Jan. 6, 2003.)

Donald Fedder gave the presentation on BOC, which included the origins of the organization, its mission and beliefs, as well as an overview of BOC's certification programs, accreditation process, and educational standards (Attachment 2-6). Following Dr. Fedder's presentation, he responded to numerous questions from the committee, among which included:

Q: Is BOC accredited by the National Commission for Certifying Agencies (NCAA)?

A: Yes

Q: How many certifies does BOC have?

A: There are 4676 total: 846 certified mastectomy fitters; 1916 certified orthotic fitters; 131 facilities; 1,186 orthotists; 186 orthotists/prosthetists; 411 prosthetists. (Information provided on Jan. 6, 2003.)

Q: How many facilities are accredited?

A: About 250-275

Q: What is the renewal process?

A: In a 3-year period, 45 hours of approved continued education must be obtained for re-certification.

Q: Does BOC require at least a high school diploma as part of its educational standards?

A: Yes, I believe so, or a GED.

Q: Would raising educational standards create a pathway for more individuals to enter the field?

A: We can't get enough candidates to enter the field in schools now. We don't have enough resources (professionals) in the industry to meet the needs of the consumers.

Q: How many certifications has BOC revoked?

A: We have a code of ethics and procedures that must be followed. We have revoked several licenses but I don't have the specific numbers.

Q: Do you know how many individuals who are practicing could sit for your exams but haven't?

A: I don't have a specific number, but perhaps thousands.

Q: Did states say why they chose ABC exams?

A: No.

After the Q&A session, the committee took a 15-minute break. When they reconvened, they reviewed definitions CMS staff prepared to assist them in their discussions (Attachment 2-8). Upon review of the terms, individual members of the committee offered the following comments:

- 1) add the word “orthotist” to the list
- 2) revisit the definition of “prosthetist”
- 3) include under the authority of the term “physician,” the citation of 1861(g) of the SSA which references Occupational Therapists (OTs) and Physical Therapists (PTs)
- 4) look at international standard definitions, as applicable, for definitions
- 5) the word “provider” is confusing with the word “supplier” in regards to the statute...revisit the word “supplier”

Per the facilitators’ advice, the committee agreed to consider the definitions provided by CMS staff as “working definitions” for discussion that would be fine-tuned at a later time.

After a short break, the committee heard presentations from the American Occupational Therapy Association (AOTA) and the American Physical Therapy Association (APTA). Representing AOTA, Deborah Slater provided the committee with an overview of the practice of occupational therapy. As part of her presentation, she described OT interventions and services, as well as their educational accreditation, preparedness related to orthotics and prosthetics (O&P), and professional requirements (Attachment 2-10). Following her presentation Ms. Slater, with assistance from committee member Leslie Lloyd, responded to a variety of committee questions, including:

Q: What coursework does OTs receive in orthotics and prosthetics?

A: Anatomy, kinesiology, neurophysiology, and related courses, along with direct classroom training in O&P.

Q: What do OTs describe as orthoses/protheses?

A: There is no specific definition used by schools but each practitioner must abide by state practice acts as well as their code of ethics.

Q: How many O&P hours are devoted in school curriculums for OTs?

A: It ranges, but approximately 68 hours of specific training in O&P.

Q: Could an individual become an OT without taking classes in applied orthotics, splinting and prosthetic design and training?

A: The course offered might not carry the same titles but the individual would have coursework that covered the content.

Q: How many members does AOTA have?

A: 47,000

Q: How many of the 47,000 members do O&P work?

A: We don't keep that statistic and it would depend on the practitioner. One could do O&P work 75% of the time and another do it only once in a while. It would depend on the setting.

Q: Do OTs do casting, pouring and vacuuming for custom fitting?

A: They often do low temperature plastics, and currently they are most often doing custom fabricated on the patient. It depends on the material and the length of the intervention.

Q: How many OTs are there nationwide?

A: We would have to research that number.

Q: Do OTs use OT assistants and/or aides?

A: Yes, but they work under the supervision of an OT.

Q: Do OTs focus on the upper extremities?

A: It depends on the setting.

Andrew Guccione delivered the presentation on physical therapists to the committee. His presentation included a discussion on the scope of practice of physical therapy, patient management, examination components, intervention components, accreditation, and licensure, among other things (Attachment 2-11). Following his presentation, Mr. Guccione responded to the committee's questions, among which included:

Q: How many PTs are in the country?

A: About 118,000. 95,000 are licensed and actively practicing.

Q: Is there any O&P work PTs can't do?

A: They can do anything they know how to do, but they obviously must stay within their legal scope of practice.

Q: Why would a PT go through the process of being certified for O/P?

A: Because it can be viewed as a specialty certification...i.e., a niche in their practice and for professional advancement they may want to stretch the limit of their knowledge.

Q: Is there a PT specialty for prosthetics or orthotics?

A: No.

Q: What percent of your examinations cover O&P?

A: 5-7%, which is the same for other specialty areas.

- Q: What is the intent of those questions?
A: They can address how a device works, its design, modification requirements. The questions can test the knowledge or skill of the applicant.
- Q: Do you say you can provide comprehensive O&P services?
A: Personally no, I do not; but, there are many PTs who do and they can get additional education.
- Q: (Question and response added on Jan. 6, 2003.) Could a beneficiary from out of state, visiting the Baltimore area, go into a PT's office to have modifications made to her prosthesis to relieve a pressure sore? Could you grind the prosthesis?
A: No, not personally, but I would do an examination as defined in the Guide for Physical Therapy Practice to first determine the cause of the sore as there may be multiple etiologies. If grinding of the prosthesis were required, as part of the intervention included in the plan of care, the beneficiary's need would be addressed by an appropriate provider.

The first day of the second Negotiated Rulemaking Committee on Special Payment Provisions for Prosthetics and Certain Custom-Fabricated Orthotics meeting closed with public comments. Randy Stevens, representative of the Pedorthic Footwear Association (PFA), thanked the committee for the opportunity he was given to address the committee at its first meeting and provided copies of PFA's Pedorthics Curriculum and 2001 Role Delineation Study Report (Attachments 2-12 and 2-12 B). A second member of the public, Ted Colaizzi, BCP, introduced himself to the committee and asked that they be sensitive to the needs of C.Peds as they undertake their work. Day one of the meeting was adjourned shortly after 5:00 p.m.

Day 2 – October 30, 2002

Two CMS staff gave presentations to the committee on the second day of the meeting. The first presentation, given by Helaine Jeffers, focused on "deemed status through accreditation." Providers are "deemed" to meet Federal regulations when inspected by organizations "deemed" to be equivalent to the Federal survey process (e.g., Joint Commission on Accreditation on Healthcare Organizations for hospitals). Ms. Jeffers walked the committee through the authority for deeming, provided regulatory cites for their reference (Attachments 2-13 and 2-13B). Staff member Joel Kaiser provided the second CMS presentation, which addressed the Healthcare Common Procedures Coding System. Mr. Kaiser explained that the system has evolved over the years and is now a national system used by CMS and insurers for billing payment. He told the committee that there is a formal process for changing Healthcare Common Procedure Codes (HCPCs) that includes review on a workgroup and national level and asked the committee to consider this fact as it relates to their work.

Following the two CMS presentations, the committee recessed so that an offline caucus could be held to discuss if a CMS representative would lead an exercise in "deconstructing" the statute and members of the committee could break for lunch.

Following lunch, National Commission on Orthotic and Prosthetic Education (NCOPE) representative Michael Brnicick addressed the committee. Mr. Brnicick's presentation included an overview of NCOPE, its purpose, composition, and accreditation process, including areas of responsibility performed by O&P credentialed professionals (Attachment 2-14). Mr. Brnicick noted in his presentation that the O&P profession requires a specialized curriculum for the Orthotist and Prosthetist and that NCOPE is the only recognized authority for educational accreditation and standard development for the O&P profession. Following his presentation, Mr. Brnicick responded to the committee's questions, among which included:

Q: Would you take an OT or PT as a member on your Board?

A: Yes, there is currently a public member who is a PT.

Q: What is the difference between CHEA and CAAHEP?

A: CHEA recognizes accrediting agencies. CAAHEP is an accrediting agency.

Q: What are the 8 institutions that have O&P programs?

A: Newington, Northwestern, Univ. of Texas, Univ. of Washington, Georgia Tech, California State, Rancho Los Amigos, and Century College.

Q: Excluding the 12-month practicum you mentioned, how long are your programs?

A: The Baccalaureate programs are 4 years. The certification programs depend on the school. For example, at Northwestern it's 5 months per discipline.

Following the Q&A session, Mr. Brnicick proceeded with the second portion of his presentation, which centered on strategies to address manpower issues in O&P. During this portion of his presentation, Mr. Brnicick informed the committee that NCOPE commissioned a manpower study in 1996 and updated it in 2002. The results of the study show that there has been an overall decline in allied health and medical school applicants and without an increase in the number of O&P graduates, the field will only be able to service 63% of the population in need by the year 2010. Among NCOPE's suggestions to address manpower issues in the O&P field are to: 1) develop new programs, 2) implement distance learning, 3) increase awareness of O&P as a profession, and 4) develop educational standards for programs for assistants and fitters.

Questions from the second portion of the NCOPE presentation were as follows:

Q: Is there a certifying component for the "privileging" process?

A: No.

Q: How is a person privileged?

A: Through the use of objective criteria, he/she is determined to be capable of delivering care without direct supervision.

- Q: Are students permitted to work under independent supervision during their residencies?
- A: They have quarterly evaluations. They follow ABC facility accreditation procedures and standards. As they go through the residency process they are allowed to do more activities independently.
- Q: Do you have minimum standards of supervision for residency programs?
- A: Not for supervision, but there are minimum standards for what residents need to experience during their residency.
- Q: Do O&P programs cover low temperature thermo-plastics in their curriculum and how much time is devoted to this topic?
- A: Each school would determine how much time it spends on each topic, but they are given guidelines for training.
- Q: Can O&P students in their residencies bill for work with a Medicare patient?
- A: Residents cannot bill and they do not “sign-off” on the patient.

At the conclusion of the NCOPE presentation, Dr. Sidney Fishman noted that the Commission of Allied Health Education Programs (CAAHEP) was established as a non-profit agency on July 1, 1994. CAAHEP accredits programs representing 18 allied health professions recognizing over 1900 allied health programs in more than 1300 institutions. These institutions include universities and colleges, academic health centers, junior community colleges, hospitals, clinics, blood banks, vocational-technical schools, proprietary institutions, and government institutions and agencies.

Following the NCOPE presentation, the committee took a short break and resumed to discuss the statute. The CMS representative, having heard objections to his proposed presentation on the statute, withdrew his offer to make same. The committee reviewed an outline of the statute prepared by the facilitators. The outline was the facilitator’s attempt to distill the statute down to its essential elements, and was intended to aid the committee in interpreting the statute.

The second day closed with a member from the audience, Ginger Clark, speaking to the committee when the floor was opened for public comment. Ms. Clark, representing the American Society of Hand Therapists, introduced herself and requested time at the next meeting to give a 10-15 minute presentation on hand therapists—noting that 65-75% of hand therapy patients receive hand orthoses. The committee agreed to hear her presentation at its third meeting.

Day 3 – October 31, 2002

The third day of the meeting began at 9:10 a.m. The committee set as its plan for the day to: 1) identify areas of the statute that they don’t need to address, 2) create workgroups for areas of the statute they will immediately address, 3) develop the agenda for its next meeting, and 4) hear public comments.

Using an outline developed by the facilitators, the committee reviewed key statements contained in the statute (Attachment 2-17). After discussion and some changes the committee agreed with the outline. The committee began a discussion of possible workgroups needed to address specific areas of the statute. Each workgroup, they decided, would include 4 to 5 people that would be tasked with doing preliminary thinking on an issue between committee meetings. The groups would then be prepared to present its findings to the entire committee when it convened next. The committee debated whether to formulate one workgroup, have multiple workgroups that worked in sequence, or have multiple workgroups that worked concurrently. Finally, they decided on the latter and designated two workgroups:

Workgroup #1: Called the “Inclusion” workgroup, this sub-group will generate a “list of items” as referenced in the statute. Specifically, the workgroup is charged with devising a process (decision tree), format, and framework for selecting items for inclusion on the list. The group will consider criteria for inclusion and will apply a sample of L-codes to its schematic for presentation to the larger committee. The following committee members will serve on this workgroup: Terry Supan, Leslie Lloyd, John Michael, Tarif Zaki, John Billock, and an ex officio CMS member. Facilitator Lynn Sylvester agreed to monitor workgroup #1’s activities.

Workgroup #2: Called the “Exclusion” workgroup, this sub-group will identify/describe items that should be clearly excluded from the “list of items” referenced in the statute, along with “fuzzy areas,” and definitions for exclusion. Committee members serving on this workgroup are Stuart Kurlander, Don Fedder, Dennis Clark, Cathy Ellis, Jim Kaiser, and an ex officio CMS member. Facilitator Ira Lobel agreed to monitor workgroup #2’s activities.

Having agreed on the workgroups, the committee developed its draft agenda for the third Negotiated Rulemaking Committee on Special Payment Provisions for Prosthetics and Certain Custom-Fabricated Orthotics meeting. Agenda items include:

- Review Minutes
- Workgroup #1&2 Reports
- Reach Consensus on Workgroup Items
- Develop New Workgroups (as needed)
- Presentation by Hand Therapists
- Public Comment

A member of the public, Mark DeHarde, spoke on the impact of the proposed rule on technology used by R&D companies serving the rehabilitation and disability community (Attachment 2-16).

The facilitators offered some closing remarks to the committee. They recognized that each of the committee members has different positions on various issues and encouraged the committee to refrain from personal attacks during its discussions and use their

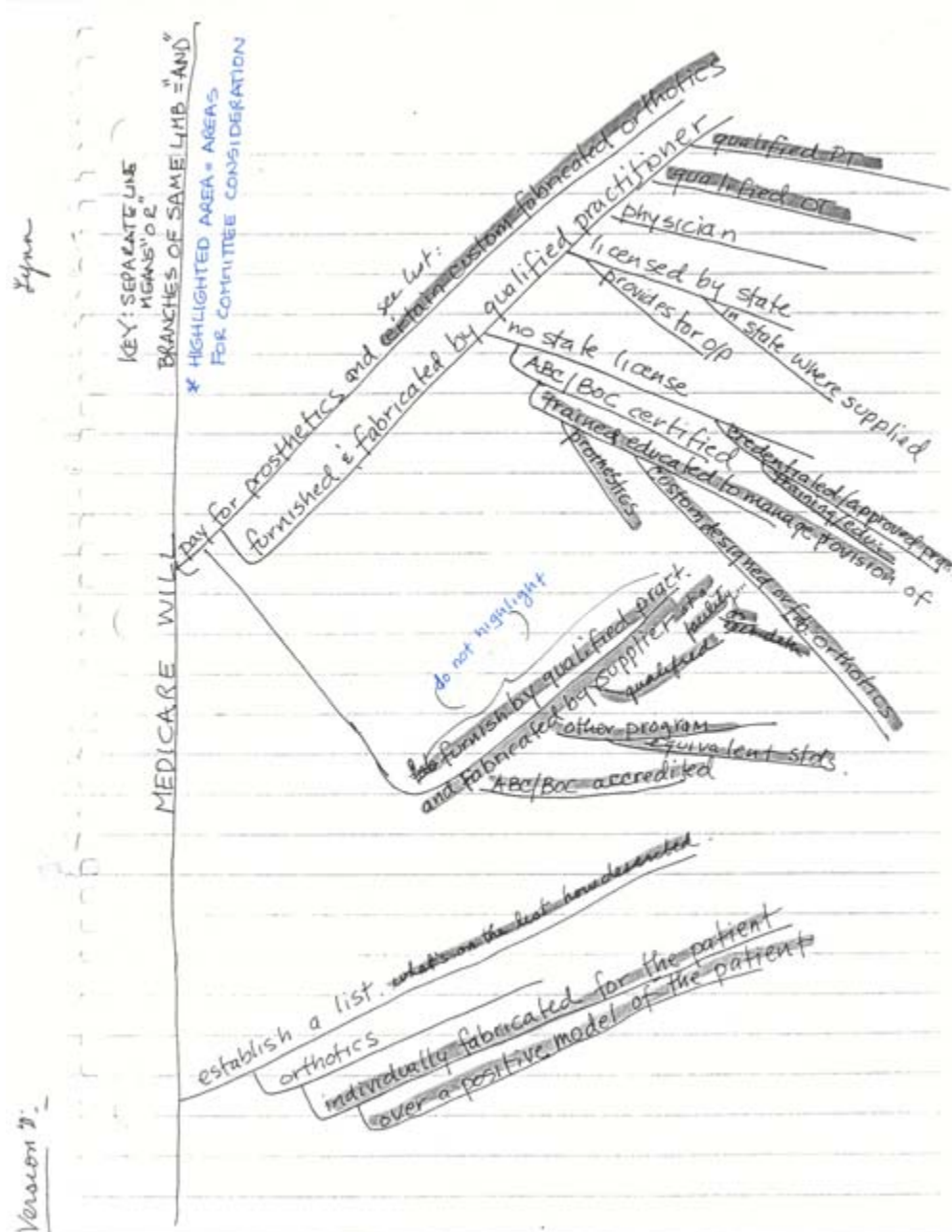
listening skills to help them keep an open mind. They also pointed out the natural transformations that occur when groups are formed and expressed optimism for the committee to continue its progression towards a fluid working group.

The facilitators reminded the committee that its next meeting will be held January 6-7, 2003, thanked them for a productive meeting, and wished them a happy holiday season.

The meeting adjourned at 12:15 p.m.

List of Attachments

2-1	Sign-In Sheet
2-2	Agenda
2-3	Philip Tamoush Correspondence
2-4	Amputee Information Exchange, Inc. Statement
2-5	American Board for Certification in Orthotics and Prosthetics Presentation
2-5b	Accreditation Manual for Orthotic and Prosthetic Patient Care Facilities (ABC)
2-5c	Canons of Ethical Conduct – Rules and Procedures (ABC)
2-5d	Practitioner Mandatory Continuing Education Book of Rules (ABC)
2-5e	Practitioner Book of Rules (ABC)
2-6	The Board for Orthotist/Prosthetist Certification Presentation
2-6b	BOC Applications and Affidavit for Facility Accreditation
2-6c	BOC Current Certificant Totals by Type as of 10/29/02
2-6d	BOC Literature Packet
2-7	AOTA Coalition Partners
2-8	CMS Definitions
2-9	Region B DMERC Supplier Manual Definition for Molded-to-Patient Model Orthosis
2-10	Occupational Therapy Presentation
2-11	The Body of Knowledge in Physical Therapy Presentation
2-12	PFA Pedorthics Curriculum and 2001 Role Delineation Study Report
2-13	Deemed Status through Accreditation Presentation
2-13b	Other Definitions
2-14	NCOPE Presentation
2-14b	Manpower Needs (NCOPE)
2-15	The Pathway to Competency (AAOP)
2-16	Ultraflex Systems Public Comment
2-17	Outline of Statue's Key Elements



Attachment 2-17